



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------------------------------------------------------------|-------------|----------------------------|---------------------|------------------|
| 09/632,074 | 08/02/2000 | Geoffrey Charles Nicholson | DAVII03.001AUS | 9705 |
| 20995 | 7590 | 07/22/2005 | EXAMINER | |
| KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614 | | | SAUD, CHRISTINE J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|-------------------------------------------------------|--|
| Office Action Summary | Application No. 09/632,074 | Applicant(s) NICHOLSON, GEOFFREY CHARLES | |
| | Examiner Christine J. Saoud | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 8-10 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) 10, 13-16 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 8-9, and 17-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/2/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 May 2005 has been entered.

Claims 1-3, 5, 8-10, 13-19 are pending in the instant application. Claims 1 and 5 have been amended and claims 4 and 6-7 have been canceled in the response filed 16 May 2005. Claims 10, 13-16 and 19 (as well as portions of claims 1-3 and 8) stand withdrawn from consideration as being drawn to a nonelected invention. The election was made without traverse in the response filed 14 October 2003.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 16 May 2005 have been fully considered but they are not deemed to be persuasive.

Requests for Interview

It is noted that Applicant's representative called the Examiner of record several times to arrange for a personal interview. The Examiner was not able to attend a personal interview on the date requested and suggested that Applicant's representative arrange a telephonic interview. At this same time, it appears that several facsimile transmissions (3 in total) were sent and placed in the record requesting personal interviews, repeating the requests made telephonically. Since the Examiner already responded to the telephonic inquiries, written response to the faxes did not seem warranted at the time.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been received in the instant application.***Claim***

Objections

Claims 1-3 are objected to for including withdrawn inventions (i.e. reference to agonists and antagonists). The continued inclusion of these inventions in the claims may lead to confusion over what is being examined. Furthermore, since the claims have been amended to recite a method of inhibiting bone resorption, the recitation of "agonist" in conjunction with "antagonist" is confusing and not enabled. Rather than raise entirely new grounds of rejection for this recitation on inventions not being examined, it is suggested that Applicant cancel this material from the claims. Applicant is reminded that the election of invention was made without traverse.

Claims 8, 9 and 18 are objected to for depending from canceled claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 recites a "method of ... delaying onset ... of bone resorption ... comprising identifying an animal with an excess of bone resorption...". If the bone resorption has already occurred, then it is not possible to delay the onset of said bone resorption. Therefore, claim 1 and dependent claims are not enabled for delaying the onset of bone resorption in an animal that already has an excess of bone resorption.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 9, and 18 depend from canceled claims. Since the text of the canceled claims is no longer present, it is not clear what the limitations of the claims are supposed to be, and the claims are indefinite.

Claim Rejections - 35 USC § 102

Claims 1-3, 5, 8-9 and 17-18 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ke et al. (U.S.Pat. No. 6,352,970) for the reasons of record in the previous Office actions.

Ke et al. teach a method of augmenting bone mass and preventing bone loss comprising the administration of leptin (see claims beginning at column 18). Ke et al. teach that leptin is useful for treatment of conditions which present with low bone mass, including osteoporosis, bone fractures, osteotomy, etc. (see column 2, lines 30-45). Ke et al. is silent to the effect of leptin on bone resorption, however, as this activity of leptin is inherent to the compound, the method of Ke et al. would inherently inhibit bone resorption via its inherent effects on osteoclasts. The instant claims require an animal with an excess of bone resorption and administration of an effective amount of leptin to inhibit or reduce bone resorption, however, it would appear these limitations are encompassed by the method of Ke et al. for augmenting bone mass and preventing bone loss. The formation of bone is a combination of bone resorption and bone formation, therefore, if the net effect is to prevent bone loss, then resorption would necessarily be inhibited. Therefore, the prior art of Ke et al. anticipates the instant claims.

Applicant presents arguments at page 4 of the response, not directly addressing them to a particular ground of rejection. Applicant states that "the treatment for Paget's disease would be to decrease bone resorption, as opposed to increasing bone formation (emphasis omitted). However, this is an over-simplification of what processes are being altered. One class of compounds which is used to treat this condition are the bisphosphonates which inhibit osteoclasts (the cells which resorb bone) but stimulate osteoblasts (the cells which produce bone). The end result is a reversal of bone loss by causing the body to produce normal bone (see page 4 of the www.arthritis.ca document). Applicant's statement that "a treatment that increases bone formation would result in even more abnormal bone formation and a treatment that reduces bone formation would result in a more weakened bone" is not supported by any facts or evidence of record.

At page 6 of the response, Applicant asserts that the method step of "identifying an animal with an excess of bone resorption" has not been met in Ke et al. This argument is not persuasive because Ke et al. is directed to treatment of a mammal in need of augmenting bone mass (i.e. with bone loss, a.k.a. having bone resorption). Specifically, Ke et al. is directed to individuals who have osteoporosis, which is encompassed by the instant claims. Therefore, this embodiment is clearly anticipated by the teachings of Ke et al. Applicant argues that Ke et al. suggest that the effect is through bone formation and therefore, the reference does not teach all the claim elements. This argument is also not persuasive for the reasons of record and for the following reasons. Ke et al. teach a method which requires administration of leptin to a

Art Unit: 1647

particular patient population. The patient population of Ke et al. is encompassed by the instant claims and specifically identified in claim 5. The compound being administered is the same as what is being administered in the instant application. The biological effect of the compound will be the same because the biological activity of leptin is inherent to the molecule. The fact that Ke et al. is silent to inhibition of bone resorption is irrelevant – this activity would have been realized by the administration of leptin, absent evidence to the contrary.

Applicant's reliance on the nature of Paget's disease is misplaced. The claims are not limited to treatment of Paget's disease, and therefore Applicant is arguing limitations not in the claims. Claim 5 includes Paget's disease, however, it is not so limited and includes osteoporosis, which is specifically taught by Ke et al.

Applicant asserts at page 8 of the response that reduction in bone resorption by leptin is a surprising result. However, unexpected results cannot overcome a rejection based on anticipation.

It is noted that the prior art of record does not suggest the administration of leptin for the inhibition of bone resorption in a patient with Paget's disease. Claims so limited appear to avoid the prior art of Ke et al.

Conclusion

No claim is allowed.

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud